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08/908,469

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/908,469	08/06/97	BACA	M P1093P1
EXAMINER			

HM12/0414

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UNGAR, S	PAPER NUMBER
ART UNIT	

1642

13

DATE MAILED: 04/14/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 2/1/99
- ☒ This action is FINAL.

- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire \_\_\_\_\_ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 34-38 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 34-38 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 469
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

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1. The Amendment filed February 1, 1999 (Paper No. 11) in response to the Office Action of August 31, 1998 (Paper No. 8) is acknowledged and has been entered. Previously pending claim 34 has been amended. Claims 34-38 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following rejections are being maintained:

***Claim Rejections - 35 USC § 103***

4. Claims 34-38 remain rejected under 35 USC 103 for the reasons previously set forth in Paper No. 8, Section 4, pages 2-4.

Applicant argues that (a) the skilled artisan would not have a reasonable expectation of success based on Ferrara alone that one could form a humanized form of the murine anti-VEGF antibody of Ferrara that would have a binding affinity of within ten-fold of the murine antibody, as claimed, (b) the instant invention provides the unexpected result of a humanized antibody for VEGF having a binding affinity of no more than  $1 \times 10^{-8}$ , © the binding affinity of the humanized hu2.0 murine antibody had 1000 fold reduction in affinity over the murine antibody. The arguments have been noted but have not been found persuasive because (a') it was well within the level of the skill in the art at the time Ferrara's invention was made to use conventional methods to produce a humanized murine anti-VEGF antibody with a binding affinity of  $1 \times 10^{-9}$  as expressly suggested by Ferrara, further, the claims are not limited to "a binding affinity of within ten-fold of the murine antibody", (b') it is clear that a binding affinity of  $1 \times 10^{-9}$  is a Kd value of "no

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more than about  $1 \times 10^{-8}$ " and since it was expressly suggested by Ferrara and conventional methods were known to produce the molecule it is clear that the results of the instant invention are not unexpected, (c') applicant is arguing limitations not recited in the claims as presently constituted.

5. All other objections and rejections recited in Paper No. 8 are withdrawn.
6. No claims allowed.
- 7 **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar

April 5, 1999



**PAULA K. HUTZELL**  
**SUPERVISORY PATENT EXAMINER**